

K162143 FixxSure® X-LinkSep 23, 2016
53 days to decisionK162143 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k162143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Aug 1, 2016
Decision date	Sep 23, 2016
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovasis, Inc.
Location	Salt Lake City, UT, US
Contact	MARSHALL MCCARTY
510(k) history	33 submissions · 32 cleared · 2004-2025

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